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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: **Kirkor Sirinyan**	Confirmation No.: **6852**
Application No.: **10/613,819**	Group Art Unit: **1623**
Filing Date: **July 3, 2003**	Examiner: **Elli Peselev**

For: **Endoparaciticidal and Ectoparasiticidal Agents**

Mail Stop Appeal-Brief Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REVISED APPEAL BRIEF IN RESPONSE TO NOTIFICATION OF NON-COMPLIANT APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37

This amended appeal brief is being filed in response to the May 20, 2010 Notice of Non-Compliant Appeal Brief requiring Appellant to submit a corrected Section V (Summary of Claimed Subject Matter), as set forth in 37 C.F.R. § 41.37(c)(1)(v). The original Appeal Brief was timely filed May 17, 2010 in support of Appellant's appeal from the final rejection of claims 11-24, dated January 4, 2010. Aside from presenting a revised section on "Summary of Claimed Subject Matter" that provides corrected citations to the originally-filed application, no new material has been added.

1. REAL PARTY IN INTEREST

The real party in interest is BAYER ANIMAL HEALTH GMBH by virtue of the assignment from BAYER AKTIENGESELLSCHAFT recorded February 5, 2009, at Reel 022213, Frame 0488.

2. RELATED APPEALS AND INTERFERENCES

No appeals or interferences are known to Appellant, Appellant's legal representative, or assignee which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending Appeal. See appendix entitled RELATED PROCEEDINGS APPENDIX.

3. STATUS OF CLAIMS

Pending: Claims 11-24

Withdrawn: None

Allowed: None

Rejected: Claims 11-24

Canceled: None

Appealed: Claims 11-24

4. STATUS OF AMENDMENTS

No amendments were filed after the Final Rejection.

5. SUMMARY OF CLAIMED SUBJECT MATTER

The following summary is for the purpose of complying with the provisions of 37 C.F.R. § 41.37(c)(1)(v). The entire disclosure should be reviewed to obtain a complete understanding of the claim language. Citations to the exemplary portions of the specification are to the specification as filed on July 3, 2003.

Claim 11

Claim features	Citations to specification
A method for treating an animal having both an endoparasitic infection and an ectoparasitic infection comprising administering to said animal a composition comprising: a therapeutically-effective amount of a first active ingredient selected from the group consisting of avermectin, 22,23-dihydroavermectin B_1, and milbemycin;	Page 2, lines 16-19; page 2, line 24 to page 3, line 1; page 19, line 3; page 19, lines 4-5
and, a therapeutically-effective amount of a second active ingredient selected from the group consisting of agonists and antagonists of the nicotinergic acetylcholine receptors of insects.	Page 2, line 24 to page 3, line 1; page 19, line 3

Claim 17

Claim features	Citations to specification
A method for treating an animal having both an endoparasitic infection and an ectoparasitic infection comprising: identifying an animal having both an	Page 2, lines 16-19; page 2, line 24 to page 3, line 1; page 19, line 3; page 19, lines 4-5; page 32, lines 4-6

endoparasitic infection and an ectoparasitic infection; and,	
administering to said identified animal a composition comprising a therapeutically-effective amount of a first active ingredient selected from the group consisting of avermectin, 22,23-dihydroavermectin B_1, and milbemycin; and,	Page 2, line 24 to page 3, line 1; page 19, line 3; page 32, lines 4-6
a therapeutically-effective amount of a second active ingredient selected from the group consisting of agonists and antagonists of the nicotinergic acetylcholine receptors of insects.	Page 2, line 24 to page 3, line 1; page 19, line 3; page 32, lines 4-6

Claim 23

Claim features	Citations to specification
A method for treating an animal having both an endoparasitic infection and an ectoparasitic infection comprising administering to said animal a composition comprising: a therapeutically-effective amount of moxidectin;	Page 2, lines 16-19; page 2, line 24 to page 3, line 1; page 7, line 2; page 19, line 3; page 19, lines 4-5
and, a therapeutically-effective amount of imidacloprid.	Page 2, line 24 to page 3, line 1; page 19, line 3

Claim 24

Claim features	Citations to specification
A method for treating an animal having both an endoparasitic infection and an ectoparasitic infection comprising:	Page 2, lines 16-19; page 2, line 24 to page 3, line 1; page 19, line 3; page 19, lines 4-5; page 32, lines 4-6

identifying an animal having both an endoparasitic infection and an ectoparasitic infection; and, administering to said animal	
a therapeutically-effective amount of moxidectin; and,	Page 7, line 2; page 19, line 3
a therapeutically-effective amount of imidacloprid.	Page 14, lines 25-26; page 19, line 3

Thus claims 11-16 and 23 are directed to treating an animal having both endo- and ecto parasitic infections by administering a single composition having at least the two recited active ingredients. Claims 17-22 and 24 differ in that they specifically recite a threshold step of first specifically identifying the animal as suffering from both forms of parasitic infection.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

- Claims 11-24 as allegedly being obvious over U.S. Pat. No. 5,712,295 to Mencke et al. ("the U.S. Mencke patent") in view of WO 96/38165 to Mencke et al. ("the Mencke publication") ***or*** in view of U.S. Pat. No. 4,199,569 to Chabala, et al. ("the Chabala patent").

7. ARGUMENT

As explained in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992) (citations omitted):

> [T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant.
>
> After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.
>
> If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent.

Thus, the Board must first determine whether the Examiner has established a *prima facie* case of unpatentability before turning to Appellant's position on appeal, because "without more[,] [Appellants] are entitled to grant of the patent." *Id.* Appellant submits that review of the Examiner's position as set forth in the Office Action demonstrates that the Examiner failed to establish a *prima facie* case of unpatentability. Assuming *arguendo* that the Examiner did establish a *prima facie* case of unpatentability, a point Appellant does not concede, Appellant submits that the Board's review of the totality of the record and the relative persuasiveness of the parties' arguments will nonetheless demonstrate the patentability of the pending claims.

Rejection of Claims 11-24 as allegedly being obvious over the U.S. Mencke patent in view of the Mencke publication *or* the Chabala patent

A. Legal Standard

In rejecting claims under 35 U.S.C. § 103, it is incumbent upon the examiner to establish a factual basis to support the legal conclusion of obviousness. *In re Fine*, 837 F.2d 1071, 1073 (Fed. Cir. 1988). In so doing, the examiner is expected to make the factual determinations set forth in *Graham v. John Deere Co.,* 383 U.S. 1, 17 (1966). A claim is obvious only when the subject matter of the claim as a whole would have been obvious to a person having ordinary skill in the art. 35 U.S.C. § 103(a).

The Federal Circuit confirmed in *Ortho McNeil Pharmaceuticals, Inc., v. Mylan Laboratories, Inc.,* 520 F.3d 1358 1364-65 (Fed. Cir. 2008) that "a flexible TSM test remains the primary guarantor against a non-statutory hindsight analysis." According to the Court, "[t]he TSM test, flexibly applied, merely assures that the obviousness test proceeds on the basis of evidence -- teachings, suggestions (a tellingly broad term), or motivations (an equally broad term) -- that arise before the time of invention as the statute requires." *Id.*

B. Analysis

The Posited Combinations of References Do Not Establish A *Prima Facie* Case of Obviousness

Although the Examiner alleges that combination of the U.S. Mencke patent and the Mencke publication ***or*** the combination of the U.S. Mencke patent and the Chabala patent renders the appealed claims obvious, the Examiner fails to provide factual basis supporting these allegations. The U.S. Mencke patent is said to disclose methods for treating endoparasitic infections with agonists and antagonists of the nicotinergic acetylcholine receptors. The Mencke publication is said to disclose methods of treating endoparasitic infections with avermectins or milbemycin, including moxidextin. The Chabala patent is said to disclose methods of treating ectoparasitic infections with avermectins. The Examiner has contended that "it would have been prima facie obvious . . . to treat an animal having both an endoparasitic infection and an ectoparasitic infection with a combination of a known anti-endoparasitic agent and a known anti-ectoparasitic agent because [a person having ordinary skill in the art] would have expected that said combination would be effective for the treatment of both infections" (1/4/10 Office Action at page 3).

In alleged support of this contention, the Examiner cites page 2, lines 16-19 of the present application, which states that at that the time the present application was filed, it was customary to protect pets against both endoparasites and ectoparasites by providing parenteral or oral treatment against the former and dermal treatment against the latter (*Id.*). Such a practice, however, is several steps removed from the present invention. The Examiner's posited reasoning makes unwarranted extensions of this reported practice to allegedly derive the present invention; in fact, the Examiner's action is not supported by any teaching or suggestion in the cited art.

First, although this old practice demonstrates it was known to treat both endoparasites and ectoparasites in the same animal, it was only known to do so using *two different* treatment types: one via oral or parenteral administration and one via dermal modality. There is no teaching or suggestion in the cited references that one could – or should even try to – modify the approach of using two different treatment types in a single animal by using a single treatment type (*e.g.*, dermal administration only or oral administration only). Indeed, the present application discloses the first-ever method for treating both endoparasites and ectoparasites using a *single* treatment modality.

Although the Examiner correctly notes that "the present claim[s] are not limited to any specific type of administration" (1/4/2010 Office Action at page 3), this observation does not affect the non-obviousness of the present claims, which recite the step of "administering ***a composition*** that comprises" **both** of the listed ingredients, thereby referring to administration of the ingredients ***together***. Thus, unlike the prior art references (whether considered individually or in combination), the present claims pertain to methods that involve simultaneous administration of ***both*** an ingredient for treating endoparasites ***and*** an ingredient for treating ectoparasites via a single treatment modality – that is, together, in "a composition" of the two, as recited. Accordingly, the Examiner's assumption of what would have allegedly been obvious is not supported by any teaching or suggestion of record, nor by an explanation from the examiner of what the ordinary artisan, of his/her own creativity, would have taken from the old treatment practices as taught by the references.

It is only with the hindsight use of Appellant's own disclosure as a template that the examiner can fit the references against the invention. Such actions or assumptions by the examiner do not support a proper *prima facie* case of obviousness. *Takeda Chem. Indus. Ltd. v.*

Alphapharm Pty., Ltd., 492 F.3d 1350, 1356-57 (Fed. Cir. 2007) (obviousness cannot be established based on a combination of references absent "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements ***in the way the claimed new invention does***") (citing *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1731 (2007); emphasis added). In this same regard, a conclusion of obviousness must be based on facts, not generalities. *In re Warner*, 379 F.2d 1011, 1017 (CCPA 1967) ("The Patent Office has the initial duty of supplying the factual basis for its rejection. It may not, [simply] because it may doubt that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in its factual basis."). *See also In re Kahn*, 441 F.3d at 988 (Fed. Cir. 2006). The lack of specificity in the Examiner's factual basis of the rejection constitutes error.

Furthermore, even if it would have been obvious to use a single treatment type (oral, parenteral, dermal) in order to administer both a medicament that is effective against endoparasites and one that is effective against ectoparasites (a point not conceded by the Appellant), there is still no evidence of record that it would have been obvious to combine both medicaments *into a single composition*, as recited in the present claims. Thus, the Examiner has drawn an unsupported conclusion not only regarding the alleged obviousness of using a single treatment type in order to treat both endo- and ectoparasites, but also regarding the alleged obviousness of combining both medicaments delineated above into a single composition. Absent particular evidence or reasoning to support this conclusion, the rejection for alleged obviousness is erroneous for this reason as well. *In re Warner*, 379 F.2d at 1017; *In re Kahn*, 441 F.3d at 988.

Moreover, even if it were assumed that it would have been obvious ***not only*** to use a single treatment type in order to administer one medicament effective against endoparasites and another effective against ectoparasites to a single animal, ***but also*** to combine both medicaments into a single composition (neither point being conceded by the Appellant), there remain two additional problems with the Examiner's position. First, the Examiner has not identified any evidence or reasoning to support the further assumption/contention that one of ordinary skill in the art would have combined the cited prior art in the posited manner. Second, the Examiner has not demonstrated that even if the combination were hypothetically made, such combination would produce the claimed invention.

The art at issue is the U.S. Mencke patent, the Mencke publication, and the Chabala patent. The Examiner has posited two possible art combinations that allegedly make the claims obvious:

(1) the combination of the U.S. Mencke patent and the Mencke publication; or

(2) the combination of the U.S. Mencke patent and the Chabala patent.

See 1/4/10 Office Action at page 2.

Regarding the first of the two proposed combinations, even if one of ordinary skill in the art were motivated to combine the respective teachings of the U.S. Mencke patent and the Mencke publication, it still would not result in any aspect of the claimed invention. Both references disclose the use of certain compounds for the treatment of ***endo***parasitic infections. But the present claims are directed to methods for the treatment of an animal having an endoparasitic infection **as well as an ectoparasitic** infection. **Neither** reference teaches or

suggests treatment of an animal having an ectoparasitic infection,[1] much less an animal having both types of infection. Any hypothetical combination of the teachings of the U.S. Mencke patent with those of the Mencke publication would, at best, result in use of a composition comprising "at least one avermectin" (per the U.S. Mencke patent; *see, e.g.*, col. 2, lines 35-41) and "agonists and antagonists of the nicotinergic acetylcholine receptors" (per the Mencke publication) in a method for the treatment of ***endo***parasites only.

The Office does not, because it can not, cite any teaching in either reference that, once the composition alleged to result from the combination of references is made, it would have been used in a method, such as claimed, administering the composition to an animal to treat **both** infections, since neither addresses endo-parasites at all. Indeed, there is nothing in this combination of references, or either one of them, that would suggest that one even take the initial step (claims 17-22, 24) of identifying an animal beset by both ecto **and** endo-parasites. Absent appropriately directed evidence of this kind, a *prima facie* case of obviousness has not been presented, and the rejection of the claims over the U.S. Mencke patent and the Mencke publication is improper.

Regarding the second of the two proposed art combinations, there is no evidence or reasoning to support the contention that one of ordinary skill in the art would have combined the U.S. Mencke patent and the Chabala patent to provide the claimed invention. Indeed, the two references teach different compounds to treat different parasites. The examiner cites nothing as to why it would have been obvious to combine the two compounds into a single composition in the first instance.

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[1] The Examiner states that "[Appellant] further contends that the cited prior art does not disclose the treatment of ectoparasitic infections" (1/4/10 Office Action at page 3, final paragraph). The Examiner misstates Appellant's position, which is that, as to the rejection based on the U.S. Mencke patent in view of the Mencke publication, neither of those two references teaches or suggests treatment of an ectoparasitic infection.

Previously, the Examiner had contended that the case of *In re Kerkhoven* provided a rationale for combining these two disparate references. 205 USPQ 1069 (CCPA 1980). But *Kerkhoven* is not directed to the situation here. Rather, *Kerkhoven* holds that "[i]t is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, *in order to form a third composition to be used for the very same purpose*" (205 USPQ at 1072, emphasis added). Here, however, unlike the facts in *Kerkhoven*, the two references do **not** have the "same purpose." More specifically, while the U.S. Mencke patent discloses compositions that are said to be effective against ***endo***parasites, the Chabala patent discloses compositions that are said to be useful for treatment of ***ecto***parasites, an entirely ***different*** purpose. Likewise, any combination of the compounds of the U.S. Mencke patent with those of the Chabala patent would not "form a third composition . . . *for the very same purpose* " as *each* of the constituent compounds individually, because the resulting "third" composition, as posited by the examiner with hindsight here, would not be for the same purpose as that of either one of the individual components. Thus, the reasoning of the *Kerkhoven* case does not apply to the posited combination of the U.S. Mencke patent and the Chabala patent. The Examiner has not provided any other factual evidence or legal support for the proposed combination of these references into a single composition for the claimed simultaneous, dual treatment, and therefore no *prima facie* case of obviousness has been established.

That the Examiner's proposed combination of the U.S. Mencke patent and the Chabala patent is in error is also seen from the Examiner's use of the "could have" standard of obviousness. *See, e.g.*, 1/4/2010 Office Action, sentence bridging pages 3-4. As stated in *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984) "[t]he mere fact a prior art reference could have

been modified does not make the modification obvious unless the prior art suggested the desirability of the modification."

As set forth in *In re Oetiker, supra*, it is the initial burden of the Examiner to establish a *prima facie* case of obviousness. It is submitted that when the Board reviews the Examiner's statement of rejection at pages 2-4 of the Final Rejection that it will readily see that the Examiner's statement of rejection is factually lacking, in error, and should be reversed.

Conclusion

For the reasons set forth above, each the Examiner's rejection is in error and should be reversed.

Date: May 25, 2010

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CLAIMS APPENDIX

11. A method for treating an animal having both an endoparasitic infection and an ectoparasitic infection comprising administering to said animal a composition comprising:

a therapeutically-effective amount of a first active ingredient selected from the group consisting of avermectin, 22,23-dihydroavermectin B_1, and milbemycin; and,

a therapeutically-effective amount of a second active ingredient selected from the group consisting of agonists and antagonists of the nicotinergic acetylcholine receptors of insects.

12. The method according to claim 11 wherein said first active ingredient comprises an avermectin, a milbemycin, or both, and said second active ingredient comprises a chloronicotinyl, a chlorothiazolyl, or both.

13. The method according to claim 11 wherein said first active ingredient comprises moxidectin.

14. The method according to claim 13 wherein said second active ingredient comprises imidacloprid.

15. The method according to claim 11 wherein said first active ingredient comprises ivermectin.

16. The method according to claim 15 wherein said second active ingredient comprises imidacloprid.

17. A method for treating an animal having both an endoparasitic infection and an ectoparasitic infection comprising:

identifying an animal having both an endoparasitic infection and an ectoparasitic infection; and,

administering to said identified animal a composition comprising

a therapeutically-effective amount of a first active ingredient selected from the group consisting of avermectin, 22,23-dihydroavermectin B_1, and milbemycin; and,

a therapeutically-effective amount of a second active ingredient selected from the group consisting of agonists and antagonists of the nicotinergic acetylcholine receptors of insects.

18. The method according to claim 17 wherein said first active ingredient comprises an avermectin, a milbemycin, or both, and said second active ingredient comprises a chloronicotinyl, a chlorothiazolyl, or both.

19. The method according to claim 17 wherein said first active ingredient comprises moxidectin.

20. The method according to claim 19 wherein said second active ingredient comprises imidacloprid.

21. The method according to claim 17 wherein said first active ingredient comprises ivermectin.

22. The method according to claim 21 wherein said second active ingredient comprises imidacloprid.

23. A method for treating an animal having both an endoparasitic infection and an ectoparasitic infection comprising administering to said animal a composition comprising: a therapeutically-effective amount of moxidectin; and, a therapeutically-effective amount of imidacloprid.

24. A method for treating an animal having both an endoparasitic infection and an ectoparasitic infection comprising:

identifying an animal having both an endoparasitic infection and an ectoparasitic infection; and,

administering to said identified animal a composition comprising

a therapeutically-effective amount of moxidectin; and,

a therapeutically-effective amount of imidacloprid.

EVIDENCE APPENDIX

None.
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RELATED PROCEEDINGS APPENDIX

None.